

Ex 33 - DC00011294-1305

Plaintiffs' Opposition to Defendants' Motion for Summary Judgment on Proximate Causation Grounds

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Supply Chain Integrity – Understanding Value

Background

Deloitte Consulting LLP

July 13, 2009

Executive Summary

Life Sciences Supply Chain – Under Attack

- The DEA would likely play a role in looking at Jackson's doctors, the drugs they prescribed and whether the doctors were registered with the DEA to prescribe those substances as federal law requires. Also, investigators are expected to look at the sources of the drugs provided to Jackson or his associates to determine if there was a pattern of trafficking. (AP 07/02/2009)
- The agency (EPA) surveyed 139 streams around the country and found that 80 percent of samples contained residues of drugs like painkillers, hormones, blood pressure medicines or antibiotics. (NY Times 04/03/2007)
- The World Health Organization estimates that the annual amount of counterfeit drug sales are between \$35 - \$40 billion per year. The World Health Organization estimates that one in three drugs on the worldwide market today is counterfeit. (ABC News 09/14/2008)
- In analysis of autopsies in 2007 released this week by the Florida Medical Examiners Commission found that the rate of deaths caused by prescription drugs was three times the rate of deaths caused by all illicit drugs combined. "You have health care providers involved, you have doctor shoppers, and then there are crimes like robbing drug shipments" said Jeff Beasley, a drug intelligence inspector for the Florida Department of Law Enforcement, which co-sponsored the study. "There is a multitude of ways to get these drugs, and that's what makes things complicated." (NY Times 06/14/2008)

Life Sciences Supply Chains—complex networks of manufacturers, wholesalers, pharmacies, benefits managers and service providers—delivering care to patients worldwide, are **losing long-held public trust**

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Executive Summary: Supply Chain Integrity—Understanding Value

The Life Sciences / Health Care industries depend on supply chains to control and deliver the right product to the right place at the right time—the consequence of failure could mean life or death. It is this requirement of “perfection” that supply chains are currently failing to meet, for various reasons. Supply Chain Integrity, while important in many industries enabling positive business results, is especially crucial in Life Sciences / Health Care industries.

- There are numerous “gaps” in the supply chain
 - Counterfeiting, Diversion for Abuse, Environmental impact, etc.—all contemporary issues that have grabbed headlines
 - As issues are resolved, they evolve to become “new” supply chain issues—the shut-down of “bad” internet pharmacies supplying legitimate pharmaceuticals for illegitimate purposes, are being replaced with pharmaceuticals being stolen “in-transit” or on site
 - The impact to business is significant—from multi-million \$ lawsuits and fines, to the increase in business expense dealing with supply chain issues
- Mitigating “risk” can be a significant driver to action, however, especially in this economic climate, mitigation **may not be enough**—investment in Supply Chain Integrity projects is not happening
 - \$Millions have been identified as the “cost” when bad things happen
 - Thousands of deaths have been attributed to supply chain challenges
 - But “value” is still not clear or compelling
- Defining the “value” of supply chain integrity—what is the impact to top line, to margin, to brand equity, and potentially other metrics—is necessary to create action, and it has not been done

For Supply Chain Integrity to gain traction, a clear and tangible value proposition needs to be developed

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Background Information

Background: Life Sciences Supply Chain Challenges

Current threats to the Life Sciences Supply Chain are numerous and constantly evolving, and future threats unknown.

- Some are unintentional: Drug Contamination, Mishandling, Expiration and Medication Error
- Some are deliberate and/or criminal: Counterfeit Drugs, Tampering, In-Transit Product Losses, Diversion for Abuse, Diversion for Profit and Black Market Trading



All are significant challenges to patient safety and the health care/life sciences industry—reducing risk from these challenges requires a collaborative and far-reaching response from the health care/life sciences industry and its partners

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Background: Supply Chain Integrity

Supply Chain Integrity is a holistic approach to the supply chain ecosystem of an industry, aimed at creating a *safe* and *secure* supply chain from manufacturer to end user (and back). It is a new approach aimed at *tightening* the supply chain enabling participants to work together to prevent and, at minimum, respond quickly to issues.

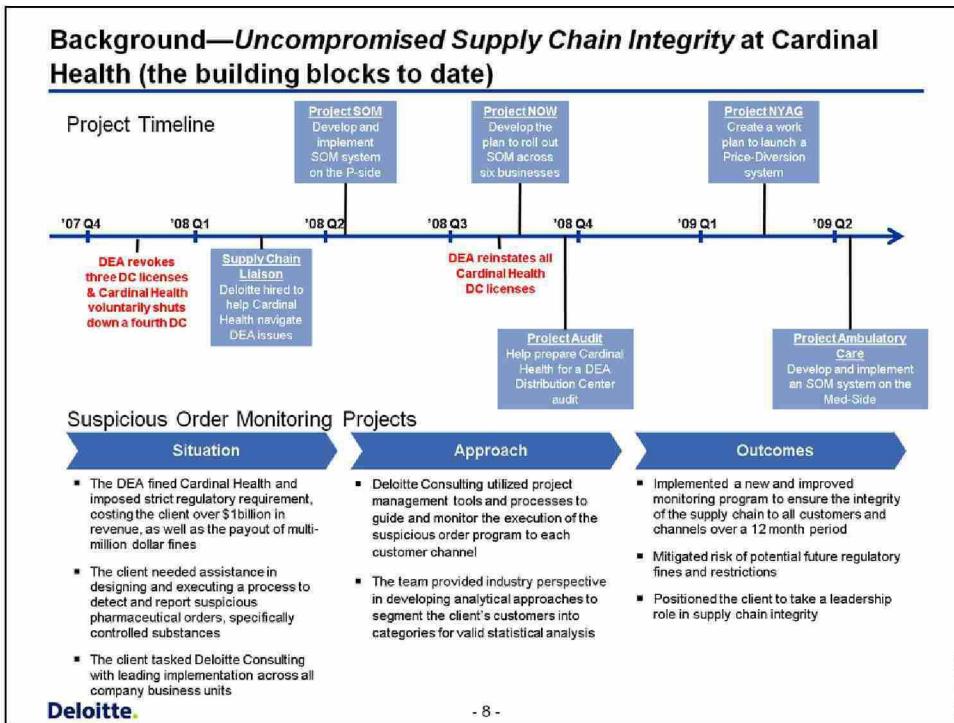


Integrity—the reliability, responsiveness, transparency and security that should be demonstrated by Life Sciences Supply Chains—can only be assured when supply chains are designed and operated to recognize and mitigate ever-changing risks.

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Background—Cardinal Health Project Descriptions

Project SOM

Suspicious Order Monitoring which included 2 threads:

- Know Your Customer – knowledge of customer's business model, history, and plans
- Electronic Monitoring – Development of a systemic way to Identify, Block and Report orders of controlled substances that are suspicious due to quantity, pattern or frequency
- Implemented across all channels of trade (approximately 30,000 customers/DEA #'s)
- Over 17,000 hours of training

Project AUDIT

The preparation of all Distribution Centers, Corporate Compliance, Sales, and Customer Service for DEA Audits

- Development of training and communication to educate, test and retest employees prior to audits
- The development of a repository to hold all important documents accessible anywhere
- The development and training of new SOP's for DC's, Sales and Corporate Compliance
- The coordination of the audits as they happened simultaneously

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Project NOW

Execution of SOM across additional Cardinal Health business units:

- The rapid execution of SOM across differing systems, business models, organizations and processes
- Implemented across 3 business units in 3 months with the capability to start-up 2 additional units at any time

Project NYAG

The development of an executable plan to transition anti-price diversion activities to existing corporate compliance organization

- Development of a workplan that would transition all processes from a project team to an existing organization
- Development of analytics that mitigated additional price diversion risk formally not monitored

Ambulatory Care

Latest project that applied current SOM methodology and systems to the Medical side of Cardinal Health

- Execute SOM across new customer channels (practitioners and surgery centers) in a different Cardinal Health business model
- Educate and train employees about pharmaceuticals, diversion, the DEA and SOM

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Background—Identified Costs at Cardinal Health (and potential Benefits)

Working with Cardinal Health on projects that have impacted the integrity of their supply chain, the following "costs" were identified. Additionally, as programs were designed and implemented to mitigate risks of the "costs" reoccurring, commentary about additional benefits were captured.

Cost Avoidance	Other Benefits
<ul style="list-style-type: none"> ▪ \$1B revenue loss in 2008 ▪ \$34M penalties for DEA ▪ \$20M+ operational improvements for DEA ▪ \$11M penalties for NYAG ▪ \$3.7M expense for NYAG ▪ Recall event estimated at \$3 - 5M ▪ In-transit loss estimated at \$1 - 3M ▪ Cold Chain excursions \$\$\$ ▪ Other litigation expenses \$\$\$ 	<ul style="list-style-type: none"> ▪ Reduction in "fat finger" orders (order errors) ▪ Normalized demand and inventory ▪ Increased customer trust (partnership) <ul style="list-style-type: none"> ▪ Recent examples with Health South; Mayo Clinic; CVS; Walgreens

Future Benefits

- **USCI is Cardinal's brand**
- Increased consumer trust
- Increased revenue
- USCI—provides a unifying brand for all Cardinal Health employees

Mitigating risks and avoiding costs is not enough—more value needs to be associated with the additional projects identified at Cardinal Health to move closer to their goal of *Uncompromised Supply Chain Integrity*

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Background—Identified Opportunities at Cardinal Health for FY10

① Order and Price Compliance Project

- SOM II IT Improvements
- SOM II Analytical and Process Improvements
- IT Redundancy
- Process/Organization Redundancy
- IT Centralization
- Strategic Communications and Training Plan
- IT Scalability Improvements
- Process/Organization Scalability Improvements
- Know Your Customer—Annual Compliance Process
- Anti-Price Diversion Transition Execution
- Anti-Price Diversion Improved Analytics

② Ambulatory Care Pharmaceutical Roll-out

- Ambulatory Care Pilot Learnings
- Ambulatory Care Roll-Out Plan

③ Pharmaceutical IT Technology Strategy

④ Audit Remediation Projects

- Increase/Enhance Investigation Capabilities
- Pre-Cyclic Audit Preparation
- Know Your Customer Completion
- Repository Improvements
- Communications to Sales and Customers of "New" Milestones
- New "Threshold" Setting Capability
- Repository Training
- On-going Analytics for DC's
- And More. . .

⑤ Operations Projects/Linkages

- Cold Chain/Ambient Storage
- In-Transit Loss
- ePedigree/Serialization
- Recall
- Others ?

⑥ "Uncompromised Supply Chain Integrity" Strategy and Plan

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Ambulatory Care has 50% turnover of customers every quarter



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